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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/451,321

11/30/1999

ROBERT H. REID

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NASH & TITUS, LLC

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MIDDLEBURG, VA 20117

EXAMINER

WILLIAMS, LEONARD M

ART UNIT

PAPER NUMBER

1617

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/451,321	Applicant(s) REID ET AL.	
	Examiner Leonard M. Williams	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/23/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-15 is/are allowed.
- 6) ☒ Claim(s) 16-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

Reissue Applications

Applicant is reminded of the continuing obligation under 37 CFR 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5693343 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b). In addition, when any substantive amendment is filed in the reissue application, which amendment otherwise places the reissue application in condition for allowance, a supplemental oath/declaration will be required. See MPEP § 1414.01.

The examiner respectfully points out the following from the MPEP regarding amendments to the claims in a reissue:

§ 1.173 Reissue specification, drawings, and amendments.

(a) Contents of a reissue application . An application for reissue must contain the entire specification, including the claims, and the drawings of the patent. No new matter shall be introduced into the application. No reissue patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent, pursuant to 35 U.S.C. 251.

(1) Specification, including claims. The entire specification, including the claims, of the patent for which reissue is requested must be furnished in the form of a copy of the printed patent, in double column format, each page on only one side of a single sheet of paper. If an amendment of the reissue application is to be included, it must be made pursuant to paragraph (b) of this section. The formal requirements for papers making up the reissue application other than those set forth in this section are set out in § 1.52.

Additionally, a copy of any disclaimer (§ 1.321), certificate of correction (§§ 1.322 through 1.324), or reexamination certificate (§ 1.570) issued in the patent must be included. (See also § 1.178).

(2) Claims . An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression "amended," "twice amended," etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without

presentation of the text of the claim.

Status of Claims

Claims 1-24 are pending in the present reissue application.

Claims 1-15 have previously been identified as allowable.

Claims 16 is rejected as set forth below.

Claims 17-24 have previously been rejected under 103(a).

The examiner notes that after an exhaustive review of the present reissue application that the 103(a) rejection over claims 17-24 is to be withdrawn and new rejections of claims 16-24 based on 35 U.S.C. 102 and 35 U.S.C. 251 are to be made. Claims 1-15 are deemed to still be free of the art and thus allowable.

This action is made non-final.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 16 is rejected under 35 U.S.C. 102(b) as being anticipated by Kent et al.
(EPO 0052510 B2).

Kent et al. teaches, on page 4, a pharmaceutical composition designed for sustained release of a drug via formation of a microcapsule of said drug with a biocompatible, biodegradable encapsulating polymer which is a poly-lactide coglycolide) copolymer anticipating the microspheres of claim 16.

The examiner respectfully points out that claim 16 is a product-by-process claim and as such patentability is dependent on the product and not how it is made. The following is an excerpt from MPEP 2113 [R-1]:

PRODUCT-BY-PROCESS CLAIMS ARE NOT LIMITED TO THE
MANIPULATIONS OF THE RECITED STEPS, ONLY THE STRUCTURE
IMPLIED BY THE STEPS

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product

does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

>The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the

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product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.)<

Claim Rejections 35 U.S.C. 251

Claims 17-24 are rejected as being based upon a defective reissue due to a lack of defect in the original patent and lack of error in obtaining the original patent under 35 U.S.C. 251 as set forth above. See 37 CFR 1.175.

The nature of the defect(s) in the lack of defect in the original patent and lack of error in obtaining the original patent is set forth in the discussion following in this Office action.

In the present case a Restriction/Election requirement was on 03/17/1995 in the parent application 08/242960. The restriction requirement was made between "a process of solvent extraction for preparing microspheres" (Group I) and "an immunostimulating composition" (Group II). In applicant's response to the restriction requirement received 04/17/1995, Group I was elected as the invention without traverse. As claims 16-24 are drawn to microspheres, an immunostimulating composition and/or a composition these claims are all drawn to a non-elected invention.

As applicants cancelled the non-elected claims in order for allowance of the elected invention claims and as applicant's did not file a divisional application for the non-elected invention it is deemed inappropriate for applicant's to "recapture" the non-elected invention via a reissue procedure.

The examiner respectfully points out the following from MPEP 1402.01:

"Where a restriction requirement was made in an application and applicant permitted the elected invention to issue as a patent without the filing of a divisional application on the non-elected invention(s), the non-elected invention(s) cannot be recovered by filing a reissue application. A reissue applicant's failure to timely file a divisional application covering the non-elected invention(s) in response to a restriction requirement is not considered to be error causing a patent granted on the elected claims to be partially inoperative by reason of claiming less than the applicant had a right to claim. Accordingly, such error is not correctable by reissue of the original patent under 35 U.S.C. 251. In re Watkinson, 900 F.2d 230, 14 USPQ2d 1407 (Fed. Cir. 1990); In re Orita, 550 F.2d 1277, 1280, 193 USPQ 145, 148 (CCPA 1977). See also In re Mead, 581 F.2d 251, 198 USPQ 412 (CCPA 1978). In this situation, the reissue claims should be rejected under 35 U.S.C. 251 for lack of defect in the original patent and lack of error in obtaining the original patent. Compare with In re Doyle, 293 F.3d 1355, 63 USPQ2d 1161 (Fed. Cir. 2002) where the court permitted the patentee to file a reissue application to present a so-called linking claim, a claim broad enough to read on or link the invention elected (and patented) together with the invention not elected. The non-elected invention(s) were inadvertently not filed as a divisional application."

Claims 17-24 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Pannu v. Storz Instruments Inc.*, 258 F.3d 1366, 59 USPQ2d 1597 (Fed. Cir. 2001); *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to claim subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope of claim subject matter surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

In the present case a Restriction/Election requirement was on 03/17/1995 in the parent application 08/242960. The restriction requirement was made between "a process of solvent extraction for preparing microspheres" (Group I) and "an immunostimulating composition" (Group II). In applicant's response to the restriction requirement received 04/17/1995, Group I was elected as the invention without traverse. As claims 16-24 are drawn to microspheres, an immunostimulating composition and/or a composition these claims are all drawn to a non-elected invention.

As applicants cancelled the non-elected claims in order for allowance of the elected invention claims and as applicant's did not file a divisional application for the non-elected invention it is deemed inappropriate for applicant's to "recapture" the non-elected invention via a reissue procedure.

The examiner respectfully points out the following from MPEP 1402.02:

"When analyzing a reissue claim for the possibility of impermissible recapture, there are two different types of analysis that must be performed. If the reissue claim "fails" either analysis, recapture exists.

First , the reissue claim must be compared to any claims canceled or amended during prosecution of the original application. It is impermissible recapture for a reissue claim to be as broad or broader in scope than any claim that was canceled or amended in the original prosecution to define over the art. Claim scope that was canceled or amended is deemed surrendered and therefore barred from reissue. In re Clement, *supra*.

Second , it must be determined whether the reissue claim entirely omits any limitation that was added/argued during the original prosecution to overcome an art rejection. Such an omission in a reissue claim, even if it includes other limitations making the reissue claim narrower than the patent claim in other aspects, is impermissible recapture. *Pannu v. Storz Instruments Inc.*, *supra*. However, if the reissue claim recites a broader form of the key limitation added/argued during original prosecution to overcome an art rejection (and therefore not entirely removing that key

limitation), then the reissue claim may not be rejected under the recapture doctrine. Ex Parte Eggert, 67 USPQ2d 1716 (Bd. Pat. App. & Inter. 2003) (precedential).

1. Comparison of Reissue Claims Narrowed/Broadened Vis- à-vis the Canceled Claims

DEFINITION: "Canceled claims," in the context of recapture case law, are claims canceled from the original application to obtain the patent for which reissue is now being sought. The claims

(A) can simply be canceled and not replaced by others, or
(B) can be canceled and replaced by other claims which are more specific than the canceled claims in at least one aspect (to thereby define over the art of record). The "replacement claims" can be new claims which are narrower than the canceled claims, or can be the same claims amended to be narrower than the canceled version of the claims.

(a) Reissue Claims are Same or Broader in Scope Than Canceled Claims in All Aspects:

The recapture rule bars the patentee from acquiring, through reissue, claims that are in all aspects (A) of the same scope as, or (B) broader in scope than, those claims canceled from the original application to obtain a patent. In re Ball Corp. v. United States, 729 F.2d at 1436, 221 USPQ at 295.

(b) Reissue Claims are Narrower in Scope Than Canceled Claims in at Least One Aspect:

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If the reissue claims are equal in scope to, or narrower than, the claims of the original patent (as opposed to the claims "canceled from the application") in all aspects, then there can never be recapture. The discussion that follows is not directed to that situation.

It is rather directed to the situation where the reissue claims are narrower than the claims 'canceled ' from the application in some aspect, but are broader than the claims of the original patent in some other aspect.

If the reissue claims are narrower in scope than the claims canceled from the original application by inclusion of the limitation added to define the original application claims over the art, there will be no recapture, even if the reissue claims are broader than the canceled claims in some other aspect (i.e., an aspect not related to the surrender made in the original application)."

Conclusion

Claims 1-15 are allowable.

Claims 16-24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

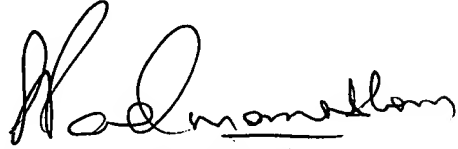
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

6/18/07